Supreme Court, U.S.
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No. 01-188

IN THE

Supreme Court of the United States

PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA,

Petitioner,

v.

KEVIN CONCANNON, COMMISSIONER, MAINE DEPARTMENT OF HUMAN SERVICES, AND G. STEVEN ROWE, ATTORNEY GENERAL OF MAINE,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the First Circuit

REPLY BRIEF OF PETITIONER

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REPLY BRIEF OF PETITIONER

In its opening brief, PhRMA anticipated and addressed most of the arguments advanced by Maine in its answering brief. Here PhRMA responds to additional arguments raised by Maine, and to certain issues raised in the *amicus* brief of the United States.

I. THE MAINE RX PROGRAM CONFLICTS WITH THE FEDERAL MEDICAID STATUTE.

A. PhRMA Has Standing To Challenge Maine's Interference With The Federal Medicaid Program.

Maine cannot and does not dispute that PhRMA satisfies Article III standing requirements with respect to its Supremacy Clause and Commerce Clause challenges to the Maine Rx statute. PhRMA's members are threatened with immediate injury that is both directly attributable to the Maine Rx scheme and redressable by the courts. See *Northeastern Fla. Chapter of Associated Gen. Contractors* v. *City of Jacksonville*, 508 U.S. 656, 663-64 (1993).

Maine nevertheless seeks to avoid a ruling on the merits of PhRMA's Supremacy Clause claim by arguing that PhRMA does not have "prudential" standing to challenge Maine Rx's conflict with federal law. See Resp. Br. at 13-14. Maine's right to make this argument is in serious doubt, because Maine did not file a cross-petition to attack the First Circuit's determination that PhRMA has prudential standing.[1] Even if properly before the Court, Maine's argument lacks merit.

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[1] Absent a cross-petition, Maine may not pursue a claim that, if successful, would require vacatur, not affirmance, of the First Circuit's decision, and would give the state greater relief than it would obtain from affirmance on the merits. *See Northwest Airlines, Inc.* v. *County of Kent, Mich.*, 510 U.S. 355, 364-65 (1994) (barring, for failure to file cross-petition, respondent's challenge to court of appeals' finding of implied

This Court and lower federal courts have decided innumerable cases in which parties claiming to be injured by a state law have challenged it as preempted by federal law. See, *e.g.*, *Shaw* v. *Delta Airlines, Inc.*, 463 U.S. 85 (1983); *Ray* v. *Atlantic Richfield Co.*, 435 U.S. 151 (1978); *City of Burbank* v. *Lockheed Air Terminal Inc.*, 411 U.S. 624 (1973). Nothing about PhRMA's preemption challenge to the Maine Rx statute warrants a departure from the practice of deciding such cases. The First Circuit correctly held, consistent with other courts of appeals, that PhRMA has prudential standing to challenge the Maine Rx statute directly under the Supremacy Clause (Pet. App. 6-8).[2]

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right of action); *Mills* v. *Electric Auto-Lite Co.*, 396 U.S. 375, 381 n.4 (1970); *see generally El Paso Nat. Gas Co.* v. *Neztsosie*, 526 U.S. 473, 479-82 & n.3 (1999) (discussing and applying "firmly entrenched rule" against "modifying judgments in favor of a nonappealing party").

The First Circuit rejected Maine's prudential standing argument without deciding a similar, but distinct, question of whether Maine had waived the argument by failing to assert it in the district court (Pet. App. 6-8 & n.3). The First Circuit noted that the courts of appeals are divided as to whether a prudential standing objection is waivable. *Compare Pershing Park Villas Homeowners Ass'n.* v. *United Pac. Ins. Co.*, 219 F.3d 895, 899 (9th Cir. 2000) ("[A] party waives objections to nonconstitutional standing not properly raised before the district court."), *and Lindley ex rel. Lindley* v. *Sullivan*, 889 F.2d 124, 129 (7th Cir. 1989) (same), *with, e.g., Thompson* v. *County of Franklin*, 15 F.3d 245, 248 (2d Cir. 1994) (rejecting waiver), *and Community First Bank* v. *National Credit Union Admin.*, 41 F.3d 1050, 1053 (6th Cir. 1994) (same).

[2] *See St. Thomas-St. John Hotel & Tourism Ass'n* v. *Government of United States Virgin Islands*, 218 F.3d 232, 241 (3d Cir. 2000) ("a state or territorial law can be unenforceable as preempted by federal law even when the federal law secures no individual substantive rights for the party arguing preemption"); *Burgio & Campofelice, Inc.* v. *NYS Dep't of Labor*, 107 F.3d 1000, 1005-07 & n.2 (2d Cir. 1997) ("'[a] claim under the Supremacy Clause that a federal law preempts a state regulation is distinct from a claim for enforcement of that federal law,'" (alteration in original) (quoting *Western Air Lines, Inc.* v. *Port Auth.*, 817 F.2d 222, 225-26 (2d Cir. 1987))); *ANR Pipeline Co.* v. *Corporation Comm'n*, 860 F.2d 1571,

PhRMA's members are directly regulated by the statute it challenges here: Maine Rx. Furthermore, PhRMA's grievance falls squarely within the "zone of interests" that the Supremacy Clause protects—the guarantee against state statutes like Maine Rx that violate "the supreme Law of the Land." See generally *Association of Data Processing Serv. Orgs., Inc.* v. *Camp*, 397 U.S. 150, 153 (1970) (stating "prudential standing" test). As the First Circuit stated, "[i]n this type of action, it is the interests protected by the Supremacy Clause, not by the preempting statute, that are at issue" (Pet. App. 7). See generally *Ex parte Young*, 209 U.S. 123, 159-60 (1908); 13B Wright et al., *Federal Practice and Procedure* § 3566, at 24 (2d ed. Supp. 2002) ("The best explanation of *Ex parte Young* and its progeny is that the Supremacy Clause creates an implied right of action for injunctive relief against state officers who are threatening to violate the federal Constitution and laws.").

Maine's reliance on *Chapman* v. *Houston Welfare Rights Organization*, 441 U.S. 600 (1979), *Dennis* v. *Higgins*, 498 U.S. 439 (1991), and *Golden State Transit Corp.* v. *City of Los Angeles*, 493 U.S. 103 (1989), is misplaced. In those cases, the Court held that that a party seeking relief under 42 U.S.C. § 1983 must demonstrate an enforceable right under a federal statute with which a challenged state law is claimed to conflict. The Court's observations in those cases were made in considering claims for relief under § 1983 (including claims for damages), not claims for relief directly under the Supremacy Clause. The Court did not hold, and has not held, that a party directly claiming a Supremacy Clause violation must demonstrate an enforceable right under the preemptive federal law. To the contrary, the Court routinely entertains such actions. When a party challenges a state law as invalid under the Supremacy Clause, the interest sought to be

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1578-81 (10th Cir. 1988) (claim that state rules conflict with federal law "sufficient ... to indicate their claims come within the zone of interest protected by the Supremacy Clause").

vindicated is an interest created not by the preempting federal law, but by the Supremacy Clause—namely, the interest in being free from burdens imposed by a state law that the Supremacy Clause declares to be a nullity because it contravenes federal law. See *Green* v. *Mansour*, 474 U.S. 64, 68 (1985) ("[r]emedies designed to end a continuing violation of federal law are necessary to vindicate" Supremacy Clause interests); *Ex parte Young*, 209 U.S. at 159-60; cf., *e.g.*, *Ray* v. *Atlantic Richfield Co.*, 435 U.S. 151 (1978) (refinery operator permitted to lodge preemption challenge to state ordinance regulating design, size, and movement of oil tankers, without consideration of whether preempting statute granted right of action); *City of Burbank* v. *Lockheed Air Terminal Inc.*, 411 U.S. 624 (1973) (airport owner permitted to lodge preemption challenge to city ordinance regulating flight schedules, without consideration of whether preempting federal statute granted private rights). PhRMA therefore has prudential standing under the Supremacy Clause to assert its preemption challenge to the Maine Rx statute.

Maine is also incorrect in asserting that PhRMA would lack prudential standing to sue directly under the federal Medicaid statute—an issue that the First Circuit did not reach. The zone of interests test for prudential standing "is not meant to be especially demanding." *Clarke* v. *Securities Indus. Ass'n*, 479 U.S. 388, 399 (1987). A party need demonstrate only that the interest it seeks to protect "is arguably within the zone of interests to be protected or regulated by the statute or constitutional guarantee in question." *Camp*, 397 U.S. at 153.

Even if PhRMA were required to show prudential standing under the Medicaid statute, PhRMA's members' interests more than satisfy this limited requirement. PhRMA's members are both "regulated" and "protected" by the Medicaid drug assistance program. Like the states, manufacturers that choose to participate in the Medicaid prescription drug program must comply with the program's regulatory requirements, including the requirement to make

Medicaid rebate payments, or face significant penalties. See 42 U.S.C. § 1396r-8(b)(3), (4) (outlining civil penalties and possibility of termination for noncompliance); cf. *Wilder* v. *Virginia Hosp. Assoc.*, 496 U.S. 498, 502 (1990); *Alexander* v. *Choate*, 469 U.S. 287, 289 n.1 (1985).[3] The Medicaid prescription drug program also protects manufacturers. The statute promises manufacturers that Medicaid will cover their drugs if they agree to pay the rebates specified by Congress. The statute also limits—both directly, through restrictions on formularies and prior authorization, see 42 U.S.C. § 1396r-8(d)(4), (5), and indirectly, through the overriding requirement that the state act in the "best interests" of Medicaid recipients, see *id.* § 1396a(a)(19)—a state's ability to restrict coverage of the drugs of participating manufacturers. PhRMA's members have substantial interests in ensuring that their drugs are made available to Medicaid beneficiaries, and that Medicaid rebate payments are made to the states on such drugs as are dispensed, in a manner consistent with the letter and purpose of the Medicaid drug program.

In short, PhRMA has "prudential standing" to challenge the Maine Rx statute, under both the Supremacy Clause and (if need be) the federal Medicaid statute.[4]

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[3] Maine's suggestion that only Maine and the federal government, the "two sovereign parties to the Medicaid 'contract,'" *see* Resp. Br. at 17, should be permitted to resolve Medicaid conflicts does not alter this conclusion. Claims arising out of Spending Clause legislation do not sound purely in contract, *see Barnes* v. *Gorman*, 122 S. Ct. 2097, 2102 n.2 (2002), and private parties may raise Supremacy Clause challenges under such legislation, *see e.g. Blum* v. *Bacon*, 457 U.S. 132, 145-46 (1982); *Carleson* v. *Remillard*, 406 U.S. 598, 604 (1972); *Townsend* v. *Swank*, 404 U.S. 282, 285 (1971).

[4] Even if PhRMA's "prudential standing" could be drawn into question, the circumstances of this case would argue strongly in favor of full adjudication of the case. Maine does not contest PhRMA's standing (constitutional or prudential) to advance its Commerce Clause challenge to the Maine Rx statute. Inevitably, then, the Court will be obliged to pass

B. Maine Rx Prior Authorization Frustrates Congress's Medicaid Objectives.

It is undisputed that under Maine Rx, Maine will be using a Medicaid procedure (prior authorization), administered by the Medicaid program using Medicaid funds, to restrict Medicaid patients' access to (and hence the sales of) certain Medicaid-participating manufacturers' drugs, unless those manufacturers pay for the Maine Rx program for other state residents.

Maine argues that Maine Rx is not preempted because the prior authorization power that Congress gave the states in the Medicaid statute need not serve that statute's objectives. See Resp. Br. at 21 (asserting that "[p]rior authorization, no matter why it may be imposed, does not contravene Medicaid"). Alternatively, Maine asserts that Maine Rx does serve federal ends, see *id.* at 24-28, such that the state law is not preempted. As the Solicitor General observes, however, the Maine program's use of prior authorization burdens Medicaid recipients, and a state may not "act contrary to the interests of Medicaid recipients as a whole to achieve goals *unrelated* to the Medicaid program." U.S. Br. at 20. Maine Rx is invalid because it burdens Medicaid and Medicaid recipients for the express purpose of assisting the non-Medicaid population of Maine.

Congress did not give states the power to restrict Medicaid patients' access to drugs in the service of non-Medicaid objectives. To the contrary, Congress expected states to use prior authorization in the "best interests of the [Medicaid] recipients," 42 U.S.C. § 1396a(a)(19), and in ways that demonstrably benefit the Medicaid program, see H.R. Rep.

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on the validity of the state law. It would be passing strange to invoke a discretionary doctrine of judicial economy, *see Bennett* v. *Spear*, 520 U.S. 154, 162 (1997), to refrain from reviewing a single claim in a case otherwise squarely before the Court. Certainly, no "prudential" interest would be served by such an approach.

No. 101-881, at 98 (1990), *reprinted in* 1990 U.S.C.C.A.N. 2017, 2110. Maine claims unfettered power to require prior authorization, bound only by the limitations set forth in 42 U.S.C. § 1396r-8(d)(5) itself. But this crabbed interpretation ignores the obligation to read the Medicaid statute, like any other statute, as a whole. See *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132-33 (2000) ("a reviewing court should not confine itself to examining a particular statutory provision in isolation" but must instead "interpret the statute as a symmetrical and coherent regulatory scheme") (internal quotation marks omitted).

Prior authorization by definition burdens Medicaid patients' access to (and hence manufacturers' sales of) prescription drugs. That burden alone, when imposed for non-Medicaid purposes, is sufficient to sustain PhRMA's preemption challenge.[5] Contrary to Maine's contention, PhRMA need not establish "that Maine Rx cannot be implemented in a manner that will not harm Medicaid patients." Resp. Br. at 23. Actual clinical harms to the health of Medicaid patients would of course amply demonstrate Maine Rx's conflict with Medicaid, but the statute's facial restrictions on access to drugs are more than sufficient.[6]

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[5] Maine's repeated invocation of *United States* v. *Salerno*, 481 U.S. 739 (1987), and its "no set of circumstances" test for facial challenges, *id.* at 745, is in vain. It is, of course, an open question whether *Salerno* properly states the standard in the first place. *See City of Chicago* v. *Morales*, 527 U.S. 41, 55 n.22 (1999) (plurality opinion). Even if it does, *Salerno*'s standard is satisfied here: Maine Rx-triggered prior authorization burdens Medicaid for non-Medicaid purposes, and thus conflicts with the federal statute, no matter how Maine may implement the prior authorization system.

[6] Maine suggests that because the procedural burden of Maine Rx prior authorization is the same as the procedural burden if prior authorization is required for Medicaid-related reasons, the Court should disregard its impact in this context. *See* Resp. Br. at 20-21. While the procedures may be the same regardless of the reason for imposing prior authorization, the magnitude of the burden they impose grows with each drug that is added

At the same time, Maine and its *amici* paint a benign picture of prior authorization, see Resp. Br. 22-24; AARP Br. at 19-23, that simply does not square with reality. Prior authorization cannot be merely a *de minimis* or innocuous procedural burden, as they suggest it is, if it is to have the powerful coercive effect on manufacturers that Maine intends. The *amicus* brief of several legal services organizations, filed on behalf of Medicaid beneficiaries and in support of neither party, is especially compelling in describing the reality of prior authorization. The brief explains that physicians, deluged by multitudes of ever-changing formularies and prior authorization requirements, not uncommonly prescribe drugs without seeking prior authorization. Even the most well-intentioned physicians may simply lack the information needed to pursue their patients' best interests. As a consequence, patients are denied coverage at the pharmacy counter, and they often receive inaccurate information about reasons for the denial.[7] See LSO Br. at 4-6. The *amicus* brief also notes that physicians aware of prior authorization requirements self-censor their prescriptions away from cutting-edge drug therapies, to the potential detriment of their patients. See *id.* at 6-7. Furthermore, these burdens are tremendously magnified for Medicaid patients, who frequently lack the financial and physical resources to navigate the prior authorization system and may simply

to the prior authorization list. Drugs that were previously readily available to Medicaid patients will now be restricted for no Medicaid reason. Indeed, if is to have the necessary coercive effect for Maine Rx purposes, prior authorization must be imposed on many drugs that were not previously subject to it, and it must be a substantial obstacle to prescription and sales of those drugs.

[7] For this reason, the data offered by *amici* in support of Maine suggesting that Maine's current prior authorization program promptly approves most requests, *see* MCSC Br. at 15-16 (citing lodging), is beside the point. Harmful consequences of prior authorization occur long before any such request is processed through the Medicaid system, if indeed it is ever submitted.

forego altogether the drugs their physicians prescribe.[8] See *id.* at 8-11.

Also without merit are Maine's contentions, in the alternative, that Maine Rx actually serves the Medicaid program. Maine makes three arguments, the first and third of which are freshly minted at this late date in the litigation, and all three of which are unpersuasive. First, Maine contends that the increased use of prior authorization, although implemented for Maine Rx purposes, will result in cost savings for the Medicaid program. See Resp. Br. at 24-25. This assertion lacks support. Prior authorization of a drug under Maine Rx is entirely unrelated to the drug's cost to the Medicaid program. It is just as likely *a priori* that manufacturers of more expensive drugs would participate in Maine Rx, while manufacturers of less expensive drugs for the same condition would not. Maine could well find itself deterring the prescription of inexpensive drugs through prior authorization, while readily covering expensive ones because the latter's manufacturers have bowed to the Maine Rx demand. In any event, no cost savings to Medicaid can be assumed.[9]

Second, Maine reiterates the First Circuit's contention that Maine Rx serves Medicaid because it may keep individuals close to the Medicaid eligibility threshold from becoming poor enough to qualify for Medicaid. See *id.* at 25. As

[8] For example, the State of Florida, in defending its Medicaid prior authorization system against a challenge by Medicaid beneficiaries, has furnished evidence that, as a consequence of prior authorization requirements, in a single month over 35,000 prescriptions were initially denied coverage, and for nearly 22,000 of those, Medicaid beneficiaries ultimately received no drugs at all in the same therapeutic class. *See Hernandez* v. *Medows*, 209 F.R.D. 665, 669 (S.D. Fla. 2002).

[9] To the extent that Maine's anticipated savings derive from Medicaid patients who are deterred from obtaining prescription drugs altogether, *see, e.g.*, note 8 *infra*, this rationale in fact highlights, rather than shields, the Maine Rx program's infirmities.

explained in PhRMA's opening brief at 25-26, this argument proves too much. By Maine's reasoning, pharmaceutical manufacturers could be forced to fund virtually any public assistance or welfare program because it might have the same kind of Medicaid "benefit." The Solicitor General also explains that Maine Rx reaches too broadly to support a credible claim of being directed to those at the Medicaid gates. See U.S. Br. at 20-22.

Finally, Maine suggests that Maine Rx will enhance the state's bargaining power if and when it negotiates with drug manufacturers for "supplemental" Medicaid rebates. See Resp. Br. at 26. PhRMA disputes Maine's premise that the federal Medicaid statute permits states to seek such rebates in the first instance, see, *e.g.*, *PhRMA* v. *Thompson*, No. 02-CV-1306 (D.D.C. filed June 28, 2002) (motion for preliminary injunction pending), and whether a state may do so is a question not before the Court in this case. In any event, a hypothetical marginal benefit to Medicaid in the event Maine later pursues this suspect, indirect strategy is inadequate to offset or justify Maine Rx prior authorization's immediate burden on the Medicaid program and its patients.

Maine's analogy to private sector pharmacy benefits managers ("PBMs") is itself flawed, because Maine is not negotiating on behalf of Maine Rx participants: it is mandating by statute that manufacturers make payments to benefit them. There is no room for market-based negotiation when one party is compelled by law to "enter into" the agreement on dictated terms. See 22 Me. Rev. Stat. Ann. § 2681(3) (Pet. App. 87).

C. Review In This Case Of Programs Other Than Maine Rx Would Be Inappropriate.

The Solicitor General agrees with PhRMA that the Maine Rx program conflicts with the federal Medicaid statute, because it "burdens the ability of Medicaid recipients to

obtain covered drugs while failing to serve Medicaid-related goals." U.S. Br. at 19.

The Solicitor General goes on, however, to invite the Court's attention to several additional issues that are not presented in this case, and that are the subject of other pending litigation—including a petition for a writ of certiorari now pending in *PhRMA* v. *Medows*, No. 02-__ (U.S. filed Dec. 5, 2002), involving a challenge by PhRMA to a Florida Medicaid program. Because none of these issues is before it in this case, the Court should resist the Solicitor General's invitation, and not opine on the validity of other state Medicaid programs and exercises of federal authority not implicated here.

First, the Solicitor General invites the Court to ratify an interpretation of the Medicaid statute that would give the states sweeping authority to impose, and the Secretary of HHS to authorize, prior authorization requirements for the purpose of extracting from manufacturers Medicaid rebates greater than those specified in the federal statute. See U.S. Br. at 15-18. This statutory issue, as the Solicitor General recognizes, is the subject of pending challenges to programs in Florida and Michigan. See *Medows*, No. 02-__ (U.S.); *Thompson*, No. 02-CV-1306 (D.D.C). Indeed, the Solicitor General even takes this opportunity cursorily to present and defend the government's litigating positions in those cases. U.S. Br. at 16-18.[10] However, the instant case raises none of

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[10] In the same vein, the Solicitor General invites the Court's attention to recent "advice" from HHS' Center for Medicare and Medicaid Services to state Medicaid directors setting out HHS' positions with regard to supplemental Medicaid rebate agreements, compliance of prior authorization requirements with clinical drug formulary safeguards, and leveraging of Medicaid prior authorization for non-Medicaid populations. *See* App. to U.S. Br. at 45a-50a. This letter, issued only two days before the filing of the U.S. brief, is a *post hoc* ratification of the government's litigating positions in the actions described herein, and, as an advisory communication, is not entitled to deference in any event. *See United*

those issues. The issue here is whether Maine may use Medicaid prior authorization to finance a *non*-Medicaid program. Florida's and Michigan's use of suspect regulatory devices (including but not limited to prior authorization) to obtain additional rebates for drugs purchased within the Medicaid program is not at issue. The statutory interpretation defended by the Solicitor General will soon be squarely before the Court in other cases, including PhRMA's petition in *Medows*, No. 02-___ (U.S.). Accordingly, the Court should decline the Solicitor General's invitation to opine broadly on HHS's authority to approve, and the states' power to implement, prior authorization programs in pursuit of "supplemental" Medicaid rebates. The only question presented here is whether a state may use Medicaid prior authorization to pursue *non*-Medicaid purposes.

Second, the Solicitor General endorses state Medicaid programs that, under the auspices of HHS's "waiver" or "demonstration project" authority, 42 U.S.C. § 1315(a), extend Medicaid prescription drug pricing to limited populations of otherwise Medicaid-ineligible patients. See U.S. Br. at 24-25. Again, the limits of the Secretary's authority to approve such programs is the subject of ongoing litigation. See, *e.g.*, *PhRMA* v. *Thompson*, 191 F. Supp. 2d 48 (D.D.C. 2002), *appeal pending*, No. 02-5110 (D.C. Cir. argued Dec. 5, 2002). The alleged statutory infirmities of those programs have no counterparts in the Maine Rx program. Again, the Court should refrain from speaking to the merits of programs whose statutory validity is not before it, and remains as yet unresolved by the lower federal courts.

Third, the Solicitor General announces here his view that HHS has the authority, if presented with a sufficient evidentiary record, to approve state programs that use

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States v. *Mead Corp.*, 533 U.S. 218, 228 (2001); *Christensen* v. *Harris County*, 529 U.S. 576, 586-87 (2000); *Bowen* v. *Georgetown Univ. Hosp.*, 488 U.S. 204, 213 (1988).

Medicaid prior authorization as leverage to coerce manufacturer discounts and rebates for *limited* non-Medicaid populations. See U.S. Br. at 28-30. Maine has not sought, and HHS has not required it to obtain, federal Medicaid clearance for the Maine Rx program. Here, at least, the Solicitor General does acknowledge that there is no reason for the Court to consider the scope of this asserted authority. *Id.* at 30. Indeed, the Solicitor General's concession is an underinclusion: it is not only the scope, but also the very existence of such authority that should be left for another day.

II. THE MAINE RX REBATES VIOLATE THE COMMERCE CLAUSE.

In addition to but distinct from its Supremacy Clause infirmities, the Maine Rx statute violates the Commerce Clause by regulating extraterritorial commerce and discriminating against out-of-state commerce and consumers in favor of in-state interests. See Pet. Br. at 26-38.

Maine seeks to defend the Maine Rx statute on the ground that Congress has authorized the state to take action that might otherwise violate the Commerce Clause—specifically, to use Medicaid prior authorization to further the Maine Rx program. See Resp. Br. at 28-29. This argument necessarily presupposes that Maine Rx prior authorization is not preempted—which it is, for the reasons outlined above. And even if Maine's use of prior authorization is not preempted, it is Maine Rx's statutorily mandated rebate payments, not the use of prior authorization as a sanction for noncompliance, that violate the Commerce Clause. Congress has done nothing to shield Maine's demands for non-Medicaid rebates from Commerce Clause scrutiny. Although Congress can empower the states to enact legislation that would otherwise violate the Commerce Clause, it "must manifest its unambiguous intent before a federal statute will be [so] read." *Wyoming* v. *Oklahoma*, 502 U.S. 437, 458 (1992); *South-Central Timber Dev., Inc.* v. *Wunnicke*, 467 U.S. 82, 91-92 (1984) (Congress must "affirmatively contemplate" otherwise

invalid state legislation; no "implied" approval will be recognized).

Nor is there traction for Maine in its continued insistence that it is merely regulating (or by analogy, taxing[11]) "retail sales activity within Maine." Resp. Br. at 40. That contention ignores the fact that the manufacturers to whom the state will be sending Maine Rx bills are not engaged in that regulated activity. They are neither sellers nor buyers in the regulated transactions, or in any in-state sales leading to those transactions, and yet they are commanded to pay the state a "rebate" on those very sales. Perhaps Maine will next charge auto manufacturers for road tolls each time the cars they manufacture are driven on Maine highways, or send bills to cell phone manufacturers based on the number of minutes Maine residents spend talking on their phones in the state. Neither scenario is any more far-fetched than charging drug manufacturers each time someone else sells their products in Maine. Maine simply lacks that authority.

Maine's rebate scheme has the direct effect—not merely an ancillary one, cf. Resp. Br. at 37—of reducing the price received by the manufacturer in its out-of-state wholesale sales of drugs that ultimately cross pharmacy counters in Maine. Were the charge levied on, say, the retail pharmacy making an in-state sale to a Maine resident, with pricing pressure passed back up the chain of commerce to impact manufacturer's profits, the extraterritorial effects on manufacturers' commercial transactions might indeed be too indirect to support a Commerce Clause challenge. Here, however, the effect is direct: Maine charges the manufacturer,

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[11] The possibility that manufacturer's promotional representatives may be present in Maine does not upset this tax analogy. They could hardly supply the required "substantial nexus" between manufacturers and the "taxed" activity: Maine pharmacies' sales of drugs to Maine Rx participants. *See Complete Auto Transit, Inc.* v. *Brady*, 430 U.S. 274, 279 (1977). Manufacturers are simply not party to those "taxed" sales.

who as a result directly experiences a different price received for drugs that it has sold outside the state. Maine thus changes the economic terms of transactions occurring wholly outside its borders, a *per se* violation of the Commerce Clause under *Brown-Forman Distillers Corp.* v. *New York State Liquor Authority*, 476 U.S. 573 (1986), *Healy* v. *Beer Institute, Inc.*, 491 U.S. 324 (1989), and *Baldwin* v. *G.A.F. Seelig, Inc.*, 294 U.S. 511 (1935).[12]

Maine's unquestioned power to regulate the terms of sale of entities that are engaged in in-state transactions does not justify its illicit effort to extend that authority beyond its borders. The "political check" that comes into play when a state seeks to tax or regulate "a significant group of state citizens" is lost when the state instead attempts to regulate outsiders. *West Lynn Creamery, Inc.* v. *Healy*, 512 U.S. 186, 200 & n.17 (1994) (internal quotation marks omitted). Commerce Clause limitations exist in part to prevent that result. *Id.*

Maine does not dispute the principle that the use of out-of-state price benchmarks is a *per se* violation under *Brown-Forman* and *Healy*. Such price tying violates the Commerce Clause because it deprives purchasers in other markets of their competitive advantages in dealing with drug manufacturers. See *Brown-Forman*, 476 U.S. at 580; *Healy*, 491 U.S. at 332-33. That dynamic will operate here as a consequence of Maine Rx, as manufacturers are forced to look beyond market conditions in California or Texas to the legal consequences of pricing decisions in those states for their pricing and payments in Maine. However, Maine seeks to shield the Maine Rx statute's price tying, 22 Me. Rev. Stat. Ann. § 2681(4) (Pet. App. 87-88), behind the statute's

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[12] Maine's suggestion that it is not affecting the "actual 'terms'" because the state will bill manufacturers quarterly and after the fact, while manufacturers make wholesale sales on an ongoing basis, *see* Resp. Br. at 36-37, is pure formalism.

instruction that the Commissioner use his "best efforts" to implement specified price benchmarks. Maine's argument ignores the coercive power inherent in the state's scheme, which eliminates the need for the Commissioner to exercise *any* "effort," best or otherwise, by commanding manufacturers to pay the rebates on pain of prior authorization, public condemnation, and even possible prosecution for profiteering.[13]

Finally, Maine Rx is protectionist and discriminatory in violation of the Commerce Clause because it externalizes the cost of a subsidy for local interests (namely, Maine Rx participants) onto out-of-state actors and their interstate commerce. See *West Lynn*, 512 U.S. at 202. The Commerce Clause does not, as Maine suggests, bar only protectionist regulation that advantages in-state interests against their out-of-state commercial competitors. See Resp. Br. at 30, 32. States can violate the Commerce Clause by advantaging not only their producers, but also their consumers, like the Maine Rx participants. See, *e.g.*, *Brown-Forman*, 476 U.S. at 580; *Camps Newfound/Owatonna, Inc.* v. *Town of Harrison*, 520 U.S. 564, 575-76 (1997). Indeed, the Court in *West Lynn* rejected just such an argument by Massachusetts that it could externalize the costs of a subsidy because the entities charged by the state were not commercial competitors of the in-state entities that received the subsidy. 512 U.S. at 202.

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[13] While certain profiteering provisions of the Maine Rx statute were preliminarily enjoined by the district court as applied to manufacturers' out-of-state sales (and Maine did not appeal that order (Pet. App. 5 n.2, 22 n.10)), others remain in force. Moreover, the very existence of the profiteering provisions evidences the coercive structure of the statute as a whole.

CONCLUSION

For the foregoing reasons and those stated in Petitioner's opening brief, the decision of the court of appeals should be reversed.

Respectfully submitted,

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